



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

703 HPI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

December 3, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gail Cowan
Director of Imaging
Columbia Brunswick Hospital
P.O. Box 139, #1 Medical Drive
Supply, NC 28462

WARNING LETTER

Dear Ms. Cowan:

Your facility was inspected on 11/19/97 by the North Carolina Division of Radiation Protection under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography as specified in Title 21 Code of Federal Regulations (CFR), Part 900.12, as follows:

The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms: [REDACTED]

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These level 2 noncompliances are:

The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [REDACTED]

Measured darkroom fog exceeded 0.05 (the measured fog level was 0.20):
Room=Mammo.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirement, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

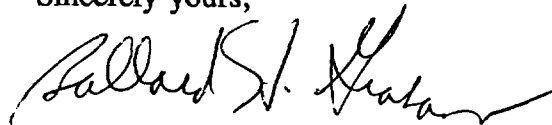
U.S. Food and Drug Administration
Compliance Enforcement
60 8th Street, N.E.
Atlanta, Georgia 30309

With a copy to:

North Carolina Department of Environment & Natural Resources
Division of Radiation Protection
3825 Barrett Drive
Raleigh, NC 27609-7221

You may choose to address both FDA and State requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call John J. McCall at (404) 347-3162.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham", with a long horizontal flourish extending to the right.

Ballard H. Graham, Director
Atlanta District